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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/509,779	SUN, YI	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *17 May 2004*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *2-6,8-17,25,26,38-40,42 and 43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2-6, 8-17, 25-26, 43, 38-40, 42-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Amendment filed May 17, 2004 in response to the Office Action of November 12, 2003 is acknowledged and has been entered. Previously pending claims 2, 8, 40, 42 have been amended and new claim 43 has been added. Claims 2-6, 8-17, 25-26, 32, 38-40, 42-43 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following objection is maintained:

Objection to the amendment of Example 19 set forth in the paper mailed November 12, 2003, Section 9, page 9 is maintained for the reasons of record.

Applicant argues that the specification in its original form asserts that oxidative buffering activity qualifies SAG as an oxygen radical scavenger. Such assertion either by present tense or by using the term may or can sufficiently provides one in the skilled art with a prediction that the protein will function as disclosed and claimed. The argument has been considered but has not been found persuasive. Applicant is misquoting the application as originally filed. The application does not assert that oxidative buffering activity qualifies SAG as an oxygen radical scavenger, rather the application states that this oxidative buffering activity **may** (emphasis added) qualify SAG as an oxygen radical scavenger. Whether or not one could predict how the protein will function is not relevant to the instant objection. The amendment to the specification alters the scope of the specification for the reasons of record. Applicant was properly required to cancel the new matter in the response to the Paper mailed November 12, 2003.

4. The following rejections are maintained:

Claim Rejections - 35 USC 112

5. Claims 6 and 12-14 remain rejected under 35 USC 112 first paragraph and newly added claim 43 is rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed November 12, 2003, Section 5, pages 3-4.

Applicant argues that the specification has been amended to identify the deposits of mSAG, hSAG-mutant1, hSAG-mutant2, and hSAG clones which bear the ATCC accession numbers 98042, 98043, 98044, 98045. The argument has been considered but has not been found persuasive because the claims are drawn to ATCC accession numbers 98402, 98403 98404, 98405 and the Application has not been amended to identify these clones. The arguments are not found persuasive and the rejection is maintained.

6. Claims 2, 4-5, 8, 10-11, 25-26, 32, 39-40, 42 remain rejected under 35 USC 112, first paragraph and newly added claim 43 is rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed November 12, 2003, Section 6, pages 4-5.

It is noted that although Applicant states that claim 39 has been amended, a review of the currently pending claims reveals that claim 39 has in fact not been amended.

Applicant argues that (a) the claims as presently amended provide sufficient descriptive support as drawn to a correlation of structure and function of the claimed DNA molecule, (b) with respect to Examiner's proposition that GCG program did not reveal any known functional domains of the polypeptide encoded by the claimed polynucleotides, Applicant respectfully submits that the GCG result alone does not negate the polypeptides specific function discovered by the present invention since

even if no functional domain is revealed, this result merely provides that the function of the protein is unknown before, which does not negate the function that is discovered by the present invention.

The arguments have been considered but have not been found persuasive because (a') the amendment of the claims to delete reference to heme binding site and to insert language drawn to maintaining the function of said polypeptide or protein does not provide a correlation between structure and function of the claimed DNA molecule. As previously set forth in Paper No. 17, a review of the specification has revealed that motif searching of the deduced protein sequences using the GCG program, did not reveal any known functional domains of the encoded polypeptides. In the absence of any known functional domains it is unclear how any correlation can be made between structure and function, (b') the specification provides no basis for the putative discovered functions other than to make a claim of function based on the GCG program findings which clearly demonstrate that no known functional domains were discovered. Although Applicant hypothesizes that the GCG program is merely one database and the functional domains of the instant encoded polypeptide may not be revealed in that database but might be found in another database, it is clear that the GCG database would be expected to be able to tease out the well known and characterized zinc-binding domain. Is Applicant suggesting that there are functional domains other than a zinc-binding domain? Is Applicant inferring that because the GCG database did not find a zinc-binding domain that indeed there is no zinc binding domain? Is so, why is Applicant claiming that the encoded polypeptide comprises a zinc-binding domain?

Applicant argues that the specification discloses that the zinc finger

domain in the SAG protein protects cells against apoptosis and that the heme binding site in the SAG protein acts as an oxygen radical scavenger to prevent oxygen radical induced damage. The argument has been considered but has not been found persuasive given the teachings drawn to the GCG database. Further, as drawn to the heme binding information in the specification, the argument is moot, given the amendments to the claims. The arguments have been considered but have not been found persuasive and the rejection is maintained.

7. Claims 2, 4-5, 10-22, 32, 38-40, 42 remain rejected under 35 USC 112, first paragraph and newly added claim 43 is rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed November 12, 2003, Section 7, pages 5-7.

Applicant argues that claim 43 is drawn to a substantial and credible utility under 35 USC 101 drawn to gene therapy for the treatment of cancer. The argument has been considered but has not been found persuasive because although the instantly claimed invention is not rejected under 35 USC 101, it is certainly rejected for the reasons previously set forth in Paper No. 17, Section 8 drawn to rejection of the previously pending claims under the enablement provisions of 35 USC 112, first paragraph.

Applicant states that it is presumed that the rejected is intended to be premised on written description grounds. It is noted for Applicant's information that the rejection first applied in Paper No. 17, Section 8, pages 5-16 and maintained in the Paper mailed November 12, 2003, Section 7, pages 5-7 is drawn to a written description rejection only insofar as the specification does not enable one skilled in the art to which it pertains, or

with which it is most nearly connected, to make/use the invention. Thus the rejection is an enablement rejection under 35 USC 112, first paragraph.

Applicant argues that the specification provides a written description of the claimed invention given that the specification teaches how to identify and clone SAG genes, the successful expression and purification of the SAG protein, the successful generation of single and double SAG mutants, the specification teaches that SAG expression protects cells from DNA fragmentation, a hallmark of apoptosis and that antisense SAG expression inhibits tumor cell growth, that it functions as an oxygen radical scavenger, SAG mutations can be used to diagnose cancer, SAG acts as a protector against lipid peroxidation, protects against neuronal apoptosis and therefore the specification has provided sufficient description, ample guidance and detailed examples for those skill in the art to make and use the claimed invention. The arguments have been considered but have not been found persuasive for the reasons of record. It is noted that Applicant does not address the issues raised in Paper No. 17 drawn to the teachings of Gura, Wang et al, Orkin et al, Marshall et al, Culver et al, Hodgson et al, Miller et al, Nature Biotechnology, all of record, drawn to gene therapy or the issues raised drawn to the teachings of Freshney et al, Dermer, both of record, drawn to the differences between cell culture and primary tissues or the issues raised drawn to the teachings of Drexler et al, Zellner et al, Embelton et al, Hsu et al drawn to cell culture artifacts or address the issues drawn to the fact that the exemplified assays are not commensurate in scope with the claimed inventions and the specific lack of guidance referred to in Paper No. 17.

Applicant reiterates previous arguments drawn to the fact that 35 USC 112, first paragraph does not require human or clinical trial data and working examples are not required. The argument has previously been considered and has not been found persuasive for the reasons of record.

Applicant argues that the references cited by Examiner drawn to clinical efficiency are general and cannot negate the specific successful invention embodied in the present claims. The argument has been considered but has not been found persuasive because Applicant has not addressed any of the teachings of the prior art or the issues raised thereby and further, the successful embodiment is not commensurate in scope with the claimed invention. The arguments have been considered but have not been found persuasive and the rejection is maintained.

8. Claims 15-17, 25-26, 32, 38 remain rejected under 35 USC 112, first paragraph and newly added claim 43 is rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed November 12, 2003, Section 8, pages 7-9.

Applicant appears to reiterate the arguments set forth above. These arguments have been considered but have not been found persuasive for the reasons previously set forth. It is noted that Applicant does not address the issue raised drawn to MPEP 2164.03. The arguments have been considered but have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC 101

9. Claims 2-6, 8-17, 25-26, 32, 38-40, 42 remain rejected under 35 USC 101 and newly added claim 43 is rejected under 35 USC 101, for the reasons previously set forth in the paper mailed November 12, 2003, Section 11, pages 10-16.

Applicant argues that for the reasons set forth above, the present invention is supported by a substantial and well-established utility and argues that in particular, the specification at page 2, lines 18-20 teaches that a better understanding of the molecular mechanisms of apoptotic induction will allow improved design of therapeutic drugs that either induce or inhibit apoptosis and that such utilities are well-documented in the art and provide a credible and substantial utility for the instantly claimed invention as a pharmaceutical composition for gene therapy.

The argument has been considered but has not been found persuasive because one would not know how to use the claimed invention in the absence of further research for the reasons set forth above and further, Applicant validates Examiner's point drawn to substantial utility in citing page 2, lines 18-20 since it is clear that additional work must be done in order to use the claimed invention for the reasons of record. Since the invention does not have substantial utility, credibility of utility cannot be established. The arguments have been considered but have not been found persuasive and the rejection is maintained.

10. Claims 2-6, 8-17, 25-26, 32, 38-40, 42 remain rejected under 35 USC 101 and newly added claim 43 is rejected under 35 USC 101, for the reasons previously set forth in the paper mailed November 12, 2003, Section 12, pages16-17.

Applicant argues that DNA is a double-stranded molecule and that the DNA molecule splits into two strands in the process of hybridization and a DNA molecule hybridizes to a protein coding sequence by the strand that is the complete complement to the protein coding regions, thus, although the complement may not encode the protein since the nucleotide sequences

would not be the same, the other strand of the DNA molecule can encode one or more domains on the protein and thus the invention is fully operative. The argument has been considered but has not been found persuasive because the claims as currently constituted recite that the hybridizing DNA molecule encodes the polypeptide comprising at least one zing finger domain and are not drawn to the other strand. As applicant correctly points out, this complete complement may not encode the protein since the nucleotide sequences would not be the same. The invention is inoperative as currently constituted. The arguments have been considered but have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC 112

11. Claims 2-6, 8-17, 25-26, 32, 38-40, 42 remain rejected under 35 USC 112, first paragraph and newly added claim 43 is rejected under 35 USC 112, first paragraph, for the reasons previously set forth in the paper mailed November 12, 2003, Section 13, pages 18-19.

Applicant argues that for the reasons set forth previously, one would know how to use the claimed invention. The argument has been considered but has not been found persuasive for the reasons set forth previously and above. The arguments have been considered but have not been found persuasive and the rejection is maintained.

12. Claims 2, 4-5, 8, 10-11, 39, 40, 42 remain rejected under 35 USC 112, first paragraph and newly added claim 43 is rejected under 35 USC 112, first paragraph, for the reasons previously set forth in the paper mailed November 12, 2003, Section 14, pages 19-20.

Applicant argues that the claims have been amended to delete reference to heme binding site. The argument has been considered but has

not been found persuasive as the rejection was drawn to both the heme binding site and to the zinc ring-finger motif. Clearly, as drawn to the heme binding site the rejection is moot, however the claims remain rejected as they are drawn to the zinc finger domain. . The arguments have been considered but have not been found persuasive and the rejection is maintained.

13. Claims 2-5, 6, (if not drawn to SEQ ID NO:3), 8, 10-11, 12-1(if not drawn to SEQ ID NO:3), 15-17, 32, 38-40 and 42 remain rejected under 35 USC 112, first paragraph and newly added claim 43 is rejected under 35 USC 112, first paragraph, for the reasons previously set forth in the paper mailed November 12, 2003, Section 15, pages 20-24.

Applicant argues that the claims have been amended to recite that the polypeptide or protein maintains its function and possesses at least one zinc finger. The argument has been considered but has not been found persuasive for the reasons of record, the specification does not teach how to use the claimed invention and the newly added functional limitations do not perfect the claims as drawn to the enablement issue given the specific rejections set forth previously and above, the specification does not teach how to use the fragments encompassed by the claims, does not teach which amino acid substitutions can be made with a reasonable expectation of maintaining function, an issue specifically raised in the paper mailed November 12, 2003, page 22 . The arguments have been considered but have not been found persuasive and the rejection is maintained.

14. Claims 25-26 remain rejected under 35 USC 112, first paragraph, for the reasons previously set forth in the paper mailed November 12, 2003, Section 16, pages 24-27.

Applicant argues again that human data is not required for enabling support under 35 USC 112, first paragraph and reiterates the teachings of the specification. The argument has been considered previously and above and is not found persuasive for the reasons of record.

15. Claims 25-26 remain rejected under 35 USC 112, first paragraph, for the reasons previously set forth in the paper mailed November 12, 2003, Section 17, pages 27-31.

Applicant argues that the specification is directed to a novel gene encoding a redox-sensitive protein that protects cells from apoptosis and promotes cell growth. Applicant further argues that the requirements of Enzo are met by the instant specification as the specification provides a written description of the claimed invention given that the specification teaches how to identify and clone SAG genes, the successful expression and purification of the SAG protein, the successful generation of single and double SAG mutants, the specification teaches that SAG expression protects cells from DNA fragmentation, a hallmark of apoptosis and that antisense SAG expression inhibits tumor cell growth, that it functions as an oxygen radical scavenger, SAG mutations can be used to diagnose cancer, SAG acts as a protector against lipid peroxidation, protects against neuronal apoptosis and therefore the specification has provided sufficient description, ample guidance and detailed examples for those skill in the art to make and use the claimed invention. The argument has been considered but has not been found persuasive because for the reasons of record none of the cited support meets the standards of either *Enzo* or *Lilly* for the reasons previously set forth. The support does not address the questions raised as to whether or not SEQ ID NO:3 in fact encodes a redox-sensitive protein, does not address the

issue raised drawn to other redox-sensitive proteins, does not address the issue raised as to which pathologies the mutations could be used to diagnose, the issue raised that the specification does not provide a description of other genes encoding a redox-sensitive protein that protects cells from apoptosis and that are useful for identifying cancer cells and thus the specification does not satisfy the Enzo standard because the specification does not disclose sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure that would identify the claimed genus. Further, the cited support does not meet the standards of Lilly since the specification describes only a single gene encoding a putative redox-sensitive protein that protects cells from apoptosis and therefore the specification necessarily fails to describe a representative number of such species and does not describe structural features common to the members of the genus, which features constitute a substantial portion of the genus. The arguments have been considered but have not been found persuasive and the rejection is maintained.

New Grounds of Objection

16. The amendment filed March 17, 2004 is objected to under 35 U.S.C. ' 132 because it introduces new matter into the specification. 35 U.S.C. ' 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Identification of the deposits of mSAG, hSAG-mutant1, hSAG-mutant2, and hSAG clones as ATCC accession numbers 98042, 98043,

98044, 98045. It is noted that the claims are drawn to ATCC accession numbers 98402, 98403, 98404, 98405.

Applicant is required to cancel the new matter in the response to this Office action.

New Grounds of Rejection

Claim Rejections - 35 USC 112

17. Claim 43 is rejected under 35 USC 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the claimed invention.

The claim is drawn to a pharmaceutical composition comprising an expression vector that promotes high expression of the antisense strand of the claimed polynucleotides in a tumor cell. This means a pharmaceutical composition for use in gene therapy applications. It is noted that inherent in a pharmaceutical composition is the *in vivo* use thereof and as drawn to the expression of the isolated and purified DNA molecule is a tumor cell, the invention is clearly drawn to gene therapy pharmaceutical compositions. The specification teaches a method of treatment of tumor cells comprising introducing into said tumor cells an expression vector comprising a DNA sequence substantially similar to the DNA sequence shown in SEQ ID Nos 1 and 3 wherein the antisense strand of the DNA sequence of SEQ ID NO:3 or 3 will be expressed at high levels in the tumor cells (para bridging pages 3-4).

One cannot extrapolate the teaching of the specification to the enablement of the claim because it was well known in the art at the time the invention was made that the status of the field of gene therapy was

unpredictable in regard to obtaining therapeutic levels of transcription in a host subject. In particular, Orkin et al (Report and Recommendations of the Panel to Assess the NIH investment in Research on Gene Therapy, 1995, of record) state that "while the expectations and the promise of gene therapy are great, clinical efficacy has not been definitively demonstrated at this time in any gene therapy protocol, despite anecdotal claims of successful therapy and the initiation of more than 100 Recombinant DNA Advisory Committee (RAC)-approved protocols" and further teach that significant problems remain in all basic aspects of gene therapy. In addition, Marshall (Science, 1995, 269:1050-1055, of record) teaches that there has been no unambiguous evidence that genetic treatment has produced therapeutic benefits" (p. 1050, col 1) and that "difficulties in getting genes transferred efficiently to target cells - and getting them expressed - remain a nagging problem for the entire field" (p. 1054, col 3). James Wilson, one skilled in the art stated that "{t}he actual vectors- how we're going to practice our trade - haven't been discovered yet" (p. 1055, col 2). Culver et al (TIG, 1994, 10:174-178, of record) reviewing gene therapy for cancer, conclude that the "primary factor hampering the widespread application of gene therapy to human disease is the lack of an efficient method for delivering genes *in situ*, and developing strategies to deliver genes to a sufficient number of tumor cells to induce complete tumor regression or restore genetic health remains a challenge " (p. 178). Further, Orkin et al reports major difficulties at the basic level include shortcomings in all current gene transfer vectors and an inadequate understanding of the biological interaction of these vectors with the host. (see page 1). None of the available vectors systems is entirely satisfactory and many of the perceived advantages of vector systems have

not been experimentally validated,(page 8). Miller et al (FASEB J., 1995, 9:190-199, of record) also review the types of vectors available for *in vivo* gene therapy, and conclude that "for the long-term success as well as the widespread applicability of human gene therapy there will have to be advances. Targeting strategies outlines in this review, which are currently only at the experimental level, will have to be translated into components of safe and highly efficient delivery systems" (p. 198, col. 1). Finally, the research community, as reported by Nature Biotechnology, 1997, 15:815, of record, has responded to the issues raised in the Orkin Report drawn to vector based delivery systems, that is the critical steps of delivery of a gene to the right cell and the subsequent maintenance of gene expression, since it is now widely appreciated that the natural tropism of a virus, while advantageous to its own replication cycle is not always optimal for a gene delivery protocol and a number of laboratories have explored methods to redirect the targeting that has evolved to ensure viral infectivity in ways that may be more suitable to the aims of gene therapy and concludes that this return to first principles should help to continue to move gene therapy in the direction of its largest and most important ambitions (p. 815). Clearly, the issues raised by the Orkin report, although being addressed, have not been resolved. Given the above it cannot be predicted from the disclosure how to use the instant pharmaceutical invention. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the that the claimed invention could be used with a reasonable

expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

18. Claims 2-5, 6, (if not drawn to SEQ ID NO:3), 8, 10-11, 12-1(if not drawn to SEQ ID NO:3), 15-17, 32, 38-40 and 42-43 are rejected under 35 USC 112, first paragraph, essentially for the reasons previously set forth in the paper mailed November 12, 2003, Section 15, pages 20-24 and further for the reasons set forth below because the specification does not teach any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are drawn to the limitations as previously set forth in the paper mailed November 12, 2003, pages 20-21. The specification teaches as set forth previously. One cannot extrapolate the teaching of the specification to the scope of the claims for the reasons set forth previously as drawn to Bowie et al, Lazar et a, Burgess et al, all of record.

Applicant's arguments drawn to the previous rejection of Claims 2-5, 6, (if not drawn to SEQ ID NO:3), 8, 10-11, 12-1(if not drawn to SEQ ID NO:3), 15-17, 32, 38-40 and 42-43 under 35 USC 112, first paragraph, previously set forth in the paper mailed November 12, 2003, Section 15, pages 20-24 are relevant to the instant rejection. In particular, since no nexus has been drawn between any functional domain and any particular structure, given the teachings of Bowie et al, Lazar et al and Burgess et al, one would not know how to make the claimed invention. The arguments were previously considered but not found persuasive for the reasons of record.

19. All other rejections and objections recited in the Paper mailed November 12, 2003 are hereby withdrawn.

20. No claims allowed.

21. Applicant's amendments necessitated the new grounds of rejection thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. ' 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers

for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
July 29, 2004